OCT 1 0 2001

Rhodia Hydrophilic Dental Impression Material

510(k) Notification

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K013140

Contact Person: Alain Morin
Market Development Manager
Rhodia Inc.
320 W. Stanley Ave.
Ventura, CA 93001

Telephone: (805) 653-5638 extension 206

Date Prepared: September 2001

Device Name and Classification:

Proprietary Name: Rhodia Hydrophilic Dental Impression Material
Common Name: Dental Impression Material
Product Code: ELW

Manufacturer:

Rhodia Chem Italia S.p.A.
Via Winckelmann, 2
20146 Milano
Italy

Device Description:

Rhodia hydrophilic dental impression material is intended for use for making intra-oral impressions. The device is a two-part vinyl polysiloxane paste with an addition-cure reaction. The base and catalyst pastes are extruded from dual-barrel cartridges through a mixing tip onto the surfaces of the teeth or onto a tray. The material quickly cures into a rigid impression. The hydrophilic property of the dental impression material helps to capture and reproduce perfect detail even in a moist environment.

Substantial Equivalence Claim:

Rhodia dental impression material is substantially equivalent to pre-amendment vinyl polysiloxane dental impression materials and has been tested according to the criteria established in the Guidance Document, "Dental Impression Materials-Premarket Notification".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2001

Mr. Alain Morin
Market Development Manager
Rhodia Incorproated
320 West Stanley Avenue
Ventura, California 93001

Re: K013140
Trade/Device Name: Rhodia Hydrophilic Dental Impression Material
Regulation Number: 872.3660
Regulation Name: Dental Impression Material
Regulatory Class: II
Product Code: ELW
Dated: September 17, 2001
Received: September 19, 2001

Dear Mr. Morin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013140

RHODIA HYDROPHILIC DENTAL IMPRESSION MATERIAL

510(k) Notification

Indications for Use Statement

510(k) Number: K013140

Device Name: Rhodia Hydrophilic Dental Impression Material

Indications for Use:

Rhodia hydrophilic dental impression materials are intended for use with PUTTY set for second impression (impression of correction) in the technique of double impression.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANTOHER PAGE AS NEEDED)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013140

Prescription Use ✓ or Over the Counter Use _____